

Application/Control Number: 09/509,377  
Applicant's response to Office Action of June 3, 2004

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**According to last Office Action Summary, „Status”, item 1.**

Examiner did not reply on the Communication filed on September 3, 2003 (see Enclosure 1), wherein my arguments were contained. Please, note that this Communication was sent in USPTO both by post (see Enclosure 2) and by fax (see Enclosure 3).

**According to last Office Action, numbered paragraph 1.**

Reference to Inventor's Certificate SU 1522466 in the first paragraph of the specification is withdrawn (see the amended specification in Enclosure 4).

**According to last Office Action, numbered paragraph 2.**

Concerning the amendment to the specification.

The amendments to the specification on page 3, line 12 filed on February 13, 2003 and September 3, 2003, are withdrawn.

Concerning the USPTO Notice of Non-Compliant Amendment of December 23, 2003.

Communication filed on September 3, 2003 was accompanied both with „Amendments to the claims” and with „Amendments to the specification”. The Office communication of December 23, 2003 required the correction and re-submission of the „Amendments to the claims” section only (see Enclosure 5). In this connection on January 19, 2004 I have filed only the corrected „Amendments to the claims” section.

**According to last Office Action, numbered paragraph 3.**

The specification is properly corrected.

**According to last Office Action, numbered paragraph 4.**

The mentioned claims are properly corrected and amended.

**According to last Office Action, numbered paragraph 6.**

- o The claims 3 and 8 are withdrawn.
- o The claims 5, 7 and 11 are amended.

**According to last Office Action, numbered paragraph 8.**

- o The grammatical errors are corrected.
- o The claim 7 describes the seal (13), but the claim 9 – the seal (29).
- o The claim 19 is dependent from the preceding one – 18th. The erroneous reference is corrected.

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According to last Office Action, numbered paragraph 10.

Claims 1-8, 10, 12, 14 and 20 are rejected „under 35 U.S.C. 102(b) as being anticipated by *Matasov*". In the previous Office Action of June 9, 2003 (paper number 20), on which refers Examiner, there was asserted: „Applicant's inventor's certificate, which was published on July 15, 1989, is prior art with respect to this application" (page 3, lines 1-2).

Here are the arguments of groundlessness of this position:

- On the title-page of inventor's certificate SU 1522466 the date July 15, 1989 is present, but this date relates to the following inscription: „Registered in the USSR State Register of Inventions". As is known, the registration of invention in the Register does not mean its print publication.
- The assertion about the publication of inventor's certificate SU 1522466 on July 15, 1989 is finally disproved by the Communication from the Federal Institute of Industrial Property of Russian Federation (Rospatent) (see Enclosure 6).
- The first disclosure of the subject matter of SU 1522466 took place on October 3, 1997 in the patent application P-97-190 (LV).
- The first publication of the subject matter of SU 1522466 took place on April 15, 1999 in the WO 99/17655.
- The first printed publication as a document itself of inventor's certificate SU 1522466 occurs only on March 31, 2003 in Online Public File Inspection EPOLINE ([www.epoline.org](http://www.epoline.org)). If there is known the other date, I kindly ask to indicate, where is possible to acquaint myself with it. According to MPEP 2128 „A reference is a „printed publication" if it is accessible to the public".
- The inventor's certificate SU 1522466 as a document was included into the set of documents at filing of the application No. 09/509,377.

The claim 20 is amended. But at the same time in said application there is no support to Examiner's opinion that „the pressurized evertng tube forms a „mechanism for introduction of an endoscopic tube which is a cylinder/piston unit connected to the pressure of gas or liquid".

According to last Office Action, numbered paragraph 11.

Claims 1-8, 12 and 20 are rejected „under 35 U.S.C. 102(b) as being anticipated by Bob et al. (U.S. Pat. 5,259,364) for the reasons set forth in numbered paragraph 12 of the previous Office Action, paper number 20".

In the numbered paragraph 12 of paper number 20 Examiner asserted: „As shown in Figure 2, the invaginator (24) would be gathered on the distal end (as the endoscope tube enters the anus (30)) by pleats (52) (col.5, lines 7-9)".

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The assertion about location of invaginator on the distal end of endoscope has no support in U.S. Pat. 5,259,364:

- o In Figure 2 there is no endoscope's distal end (38) at all, at the same time the distal (relatively to anus (30)) part (2) of tube is represented without „pleats (52)“.
- o In Figure 2 there is shown that the slit between means (70) and roller pairs (72) under no circumstances will not pass „pleats (52)“ „on the distal end“ of endoscope.
- o Also in Figure 1 there is no any „pleats (52)“ on the distal end of tube (2).
- o The extract cited by Examiner had no connection with the „gathering of invaginator (24)“ and with the „pleats (52)“. Please, note that the U.S. Pat. 5,259,364 does not contain any data about gathering of „invaginator (24)“ at all.

In the U.S. Pat. 5,259,364 there is unambiguously stated:

- o „supply portion is disposed in a pressure chamber“ (claim 4).
- o „The rearward, in FIG. 2 lower end of the supply portion 52 is attached to the rear wall of pressure chamber 50.“ (col. 5, lines 7-9).

These citations demonstrate the fundamental differences between compared invaginators:

- o the supply portion (52) of invaginator according to U.S. Pat. 5,259,364 is disposed in the chamber (50) and is attached to it.
- o the Invaginator (23) according to the present application is attached to the endoscope tube (3) and is disposed on it.

These differences give the following results:

- o the supply portion (52) of invaginator according to U.S. Pat. 5,259,364 is always located in the chamber (50).
- o the Invaginator (23) according to present application moves into the colon on the distal part of endoscope tube (3).

In the numbered paragraph 12 of paper number 20 there was asserted: „As to claims 2, 3 and 8, pleats (52) form a compact hollow cylinder which defines a gap (note a space between pleats and endoscope tube in Figure 2), that is maintained under working pressure (col.5, lines 18-22)“.

On the Figure 2, proposed by Examiner, the space (68 and 44) is formed solely by fluid pressure, and in the U.S. Pat. 5,259,364 on col.3, lines 30-36 is said: „It is possible to apply fluid pressure to the annular space between the inner portion of the hollow member and the endoscope tube during introduction. Frictional engagement with an undesirably high pressing force between the inner portion of the hollow member and the outer circumference of the endoscope tube can be avoided in this manner“.

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Examiner mistakenly considered that the present application also comprises a „fluid“ solution of the problem of „frictional engagement“.

- o „working pressure maintains gap 25“ (Office Action of November 20, 2002);
- o „the working pressure is applied to gap 25“ (Office Action of June 9, 2003, paragraph 4 (b)).

There is no any support to these assertions: the seal (29) insulates the gap (25) from the cavity (14) with working pressure (see English translation of WO 99/17655, page 5 lines 11-12).

My solution of the problem of „frictional engagement“ – invaginator (23) in the shape of a compact hollow cylinder having a gap (25) with endoscope tube (3), the cylinder *“is formed of a crumpled and tightly compressed in longitudinal and transverse directions short layers of different forms of an eversible thin-walled tube placed at different angles with the longitudinal axis of an endoscopic tube”* (see English translation of WO 99/17655, page 3 lines 23-26).

In the U.S. Pat. 5,259,364 there is not a word about compact cylinder with a gap:

- o there are no terms *“compact”, “cylinder”, “formed”* and word-combinations *“compact cylinder”, “compact hollow cylinder”*;
- o there are no analogues to Examiner's phrase *“pleats (52) form a compact hollow cylinder”*;
- o there are no analogues to Examiner's assertion that *“cylinder... define a gap”*;
- o the supply portion (52) on the Figure 2, indicated by Examiner, is represented by a wavy line. Hollow cylinders are represented by straight lines – see, for example, the invaginator (23) on Figures 1c, 1e, 1f of the present application.

Thus:

- o In the U.S. Pat. 5,259,364 the space (68, 44) is formed by fluid pressure.
- o In the present application the gap (25) is ensured by molding (forming) of eversible tube.

In the numbered paragraph 12 of paper number 20 there was asserted: *„As to claim 4, the distal end (38) of the endoscope tube encloses a camera and is thus inherently sealed”*.

In the claim 4 mentioned by Examiner, concerns the separate removable element – the seal (29) between an endoscope tube and unverted end of invaginator. In the amended Claims about this seal is said in claim 6.

In the numbered paragraph 12 of paper number 20 there is a note: *„As to claim 5, note shell (50).*

Please, note that the pressure chamber (50) according to the U.S. Pat. 5,259,364 neither by construction nor by functionally have nothing common with the shell (22) according to the present application:

- o in the chamber (50) the means (70, 72) are disposed,

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The tip (6) according to the present application together with the protective glass (33) is removable, separate from endoscope tube (3) as hat from head, disposable element.

**According to last Office Action, numbered paragraph 11:**

In numbered paragraph 11 is asserted: „As to claim 20, the pressurized everting tube forms a „mechanism for introduction of an endoscopic tube which is a cylinder/piston unit connected to the pressure of gas or liquid”.

The claim 20 is amended. However the opinion that invaginator forms a cylinder/piston unit does not have support in the specification of the present application.

**According to last Office Action, numbered paragraph 13.**

The claim 16 is rejected „under 35 U.S.C. 103(a) as being unpatentable over Matasov (SU 1522466) in view of Wilk et al. (U.S. Pat. 5,396,879) and further as being unpatentable over Bob et al. in view of Wilk et al. for the reasons set forth ”.

The rejection of claim 16 over SU 1522466 in view of U.S. Pat. 5,396,879 is invalid as SU 1522466 is the component part of the present application – see the reply according to the paragraph 10.

The rejection of claim 16 over U.S. Pat. 5,259,364 in view of U.S. Pat. 5,396,879 is invalid as U.S. Pat. 5,259,364 has no common features with claims 1, 2, 3, 7, 8 of the Claims filed on September 3, 2003.

**According to last Office Action, numbered paragraph 14.**

Examiner asserts, that applicant provided no arguments. It is not the case. About the Communication of September 3, 2003 (see Enclosure 1), where my arguments were cited, Examiner for some reason does not mention in his action of June 3, 2004. Please, note that this Communication was sent in USPTO both by post (see Enclosure 2) and by fax (see Enclosure 3).

In order to make easier Examiner's work, herewith is enclosed the table of support for the amended claims (see Enclosure 12).

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According to item 1.

Thank You for the advice. I have consulted the US registered patent attorney and the European patent attorney. They affirm, that the main problem is in the infringement of 35 U.S.C. 102 (b) at granting of US Patent 6,485,409 (Voloshin et al.).

According to item 2.

Subject of discussion:	Examiner on June 9, 2003:	Applicant on September 3, 2003:
Status of the SU Inventor's Certificate No.1522466.	"... Applicant's inventor's certificate, which was published on July 15, 1989, is prior art with respect to this application".	<p>The statement of Examiner about publication of SU Inventors Certificate No. 1522466 on July 15, 1989 does not square with reality.</p> <p><b>In reality:</b></p> <ul style="list-style-type: none"> <li>On February 13, 2003 Examiner received the certificated copy and the English translation of SU Inventors Certificate No. 1522466, which has a stamp "For office use only".</li> <li>In the Official Bulletin of the State Committee of Inventions and Discoveries at the USSR State Committee of Science and Engineering No. 42 from November 15, 1989 is said, that the inventors certificates from No. 1522442 till No. 1523037 are not to be published (see Enclosure No.1).</li> <li>The SU Inventors Certificate No. 1522466 was published after October 3, 1997 (see PCT Gazette 15/1999 from April 15, 1999, publication WO99/17655) and therefore is not prior art, but the component part of this application.</li> </ul>

According to item 3.

Thank You for the approval of proposed drawing. Corrected drawing is enclosed (see Enclosure No.2)

According to item 4 (a).

Thank You for the observation. The dot is applied. The newly added sentences on page-3 are amended (see Enclosure No. 3).

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According to items 4 (a) and (b). (Repeatedly, for the first time in my letter from February 13, 2003).

Subject of discussion:	Examiner:	Applicant on September 3, 2003:
Examiner's statement concerning the including in the specification of new subject matter: "the working pressure is applied to gap 25".	<ul style="list-style-type: none"> <li>• "the working pressure keep the gap 25" (Office Action from November 20, 2002)</li> <li>• "working pressure is applied to gap 25" (Office Action from June 9, 2003)</li> <li>• "the newly added sentences on page 3 ... are indefinite as to meaning" (Office Action from June 9, 2003)</li> </ul>	<p>The statements of Examiner "the working pressure keeps the gap 25" and "the working pressure applied to gap 25" do not square with reality.</p> <p>In reality:</p> <ul style="list-style-type: none"> <li>• In my application on page 3 and page 5 there is no and could not be the statement of Examiner.</li> <li>• Examiner has at first distorted ("the working pressure keeps the gap 25", "the working pressure applied to gap 25" ) the subject matter of claim 3 (8), and then begin to allege, that this (distorted) subject matter was not in the specification as originally filed.</li> <li>• The working pressure exerts influence upon all the elements, which are limiting its cavity and, as a result, presses the uneverted part of invaginator to the endoscopic tube. The problem of gap's maintaining exists for all the endoscopes, comprising an invaginator (see page 1, lines 12-15, 36-40 of the application PCT/LV98/00006).</li> <li>• US Patent 5,259,364 (Bob et al.) declares the maintaining of gap by means of pressure. The pressure is forced simultaneously into two cavities: into the chamber (42) of the everted part of invaginator and into the gap space (44) between the invaginator (32) and endoscopic tube (2).</li> <li>• In my application the working pressure is introduced only into one cavity (14).</li> <li>• In my application the working pressure into the gap (25) - that is the cavity between invaginator and endoscopic tube - is not feeded. It is inadmissible. The gap (25) is kept by the invaginator formed in a hollow cylinder (23), which has a definite compactness. The working pressure in cavity (14) is not able to grasp the compact cylinder (23), in other words - to</li> </ul>

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		liquidate its gap (25) with the endoscopic tube (3). <ul style="list-style-type: none"> <li>• The real subject matter of claims 3 and 8 was fully and clearly described in the application at the time it was filed. Please note the application PCT/LV98/00006:</li> <li>• page 3 lines 18-19 and 23-26;</li> <li>• page 5 lines 7-9;</li> <li>• page 7 lines 38-40;</li> <li>• page 9 lines 11-13;</li> <li>• page 10 lines 1-3;</li> <li>• Fig. 1 c, 1 e, 1 f;</li> <li>• Abstract, lines 2, 3.</li> </ul>
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Herewith I propose the correction of lines 15-19 on page 3, where the mentioning of pressure is excluded:  
*The stability of diameters depends on the compactness of the cylinder. In one of the embodiments the definite compactness of cylinder ensures the gap with endoscopic tube during their joining and in the process of invagination, in the other – only during the joining. There are possible also the interim variants of embodiments.*

According to item 5.

Concerning claim 1. The amended claim looks like as follows:

1. *An endoscope, comprising an invaginator which is a thin-walled tube, compactly placed on the distal part of an endoscopic tube in the shape of small layers and/or pleats.*

Concerning claim 2. The amended claim looks like as follows:

2. *The endoscope according to claim 1, wherein said invaginator is formed in the shape of a compact hollow cylinder, which has a gap with the distal part of the endoscopic tube.*

Concerning claims 3, 5, 7, 8, 10, 16 and 17. Thank You for the proposals. They are accepted.

According to item 7. (Repeatedly, for the first time in my letter from February 13, 2003).

Subject of discussion:	Examiner on June 9, 2003:	Applicant on September 3, 2003:
Claims 3 and 8 and description of their subject matter in the specification.	"Claims contains subject matter which was not described in the specification in	The statements of Examiner "the working pressure keeps the gap 25" and "the working pressure applied to gap 25" do not square with reality. In reality: <ul style="list-style-type: none"> <li>• Examiner has at first distorted ("the working pressure keeps</li> </ul>



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	such a way ... "	<p>the gap 25", "the working pressure applied to gap 25") the subject matter of claim 3 (8), and then begin to allege, that this (distorted) subject matter was not described in the specification in comply with the 35 U.S.C. 112, first paragraph.</p> <ul style="list-style-type: none"> <li>• In my application there is no and could not be the description of subject matter, distorted by Examiner.</li> <li>• The working pressure, which exerts influence upon all the elements limiting its cavity, presses the uneverted part of invaginator to the endoscopic tube. This problem is typical for all the endoscopes, comprising an invaginator (see page 1, lines 12-15, 38-41 of the application PCT/LV98/00006).</li> <li>• US Patent 5,259,364 (Bob et al.) declares the solving of this problem by means of pressure, which is forced not only into the chamber (42) of the everted part (26) of invaginator, but also into the gap space (44) between the invaginator (32) and endoscopic tube (2).</li> <li>• In my application the working pressure into the cavity (25) is not feeded. It is inadmissible. The gap (25) is kept by the invaginator formed in a hollow cylinder (23), which has a definite compactness. The working pressure in cavity (14) is not able to grasp the compact cylinder (23), in other words - to liquidate its gap (25) with the endoscopic tube (3).</li> <li>• In my application the real subject matter of claims 3 and 8 was fully and clearly described in the application at the time it was filed. Please note the application PCT/LV98/00006:           <ul style="list-style-type: none"> <li>• page 3 lines 18-19 and 23-26;</li> <li>• page 5 lines 7-9;</li> <li>• page 7 lines 38-40;</li> <li>• page 9 lines 11-13;</li> <li>• page 10 lines 1-3;</li> <li>• Fig. 1 c, 1 e, 1 f;</li> <li>• Abstract, lines 2, 3.</li> </ul> </li> </ul>
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Herewith I propose the correction of lines 15-19 on page 3, where the mentioning of pressure is excluded:  
*The stability of diameters depends on the compactness of the cylinder. In one of the embodiments the definite compactness of cylinder ensures the gap with endoscopic tube during their joining and in the process of invagination, in the other - only during the joining. There are possible also the interim variants of embodiments.*

According to item 9. Thank You for the observations. They are accepted.

Concerning claim 3. The amended claim looks like as follows:

3. *The endoscope according to claim 2, wherein said cylinder has a compactness, which ensures said gap in the process of invagination of the endoscopic tube.*

Concerning claim 8. The amended claim looks like as follows:

8. *The endoscope according to claim 7, wherein said cylinder has a compactness, which ensures said gap in the process of invagination of the endoscopic tube.*

Concerning claim 13. The amended claim looks like as follows:

13. *The endoscope according to claim 12, wherein a cavity of said tip communicates with a cavity of intestines.*

Concerning claim 15. The claim 15 is withdrawn.

Concerning claim 16. Thank You for the observation. The amended claim looks like as follows:

- *The endoscope according to any of claims 1, 2, 3, 7, 8, wherein the endoscopic tube further comprises a distal drives of traction lines, bending its distal end, which are cylinder-piston units, connected to the pressure of gas or liquid.*

Concerning claim 17. The claim 17 is withdrawn.

Concerning claim 18. The subject matters of this claim are following:

1. *the biopsy forceps, which are the flexible hermetic tube,*
2. *the piston of biopsy channel, which is placed on the distal end of the flexible hermetic tube.*

These subject matters are illustrated on Fig. 4d under the numbers 63-68 and described in the specification on:

- page 4, lines 13-16;
- page 5, lines 28-30;
- page 6, lines 38-43;
- page 8, lines 17-22.

Concerning claim 19. Thank you for the observation. The amended claim looks like as follows:

- *The endoscope according to claim 16, further comprising a distal drive of traction line of a cutters of said biopsy forceps.*

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According to item 11.

Subject of discussion:	Examiner on June 9, 2003:	Applicant on September 3, 2003:
The status of SU Inventors Certificate No.1522466.	"Claims 1, 2, 4-7, 9-12, 14 and 20 are rejected under 35 USC 102 (b) as being anticipated by Matasov"	<p>The statement about publication of SU Inventors Certificate No. 1522466 on July 15, 1989 does not square with reality.</p> <p>In reality:</p> <ul style="list-style-type: none"> <li>On February 13, 2003 Examiner received the certificated copy and the English translation of SU Inventors Certificate No. 1522466, which has a stamp "For office use only".</li> <li>In the Official Bulletin of the State Committee of Inventions and Discoveries at the USSR State Committee of Science and Engineering No. 42 from November 15, 1989 is said that the inventors certificates from No. 1522442 till No. 1523037 are not to be published (see Enclosure No.1).</li> <li>The SU Inventors Certificate No. 1522466 was published after October 3, 1997 (see PCT Gazette 15/1999 from April 15, 1999, publication WO99/17655) and therefore is not prior art, but the component part of this application.</li> <li>Examiner has greatly distorted the contents of the SU Inventors Certificate No. 1522466, but its status (as the component part of my application) excludes the necessity of discussion.</li> </ul>

According to item 12. (Repeatedly, for the first time in my letter from February 13, 2003).

Examiner has rejected the claims 1-9, 11, 12 and 20 under 35 USC § 102 (b), as being anticipated by Bob et al. (U.S. Pat. 5,259,364).

Herewith I repeatedly adduce the proofs, that the subject matters of claims 1-9, 11, 12 and 20 (from February 13, 2003) of my application have not any common features with U.S. Pat. 5,259,364 (Bob et al.).

Subject of discussion:	Examiner on June 9, 2003:	Applicant on September 3, 2003:
Examiner's statement, that	" As shown on Figure 2, the	The statement of Examiner, that the invaginator according to US Patent 5,259,364 (Bob et al.) "would be gathered on the distal

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the invaginator according the US Patent 5,259,364 "would be gathered on the distal end".	invaginator (24) would be gathered on the distal end (as the endoscope tube enters the anus 30) by pleats (52) (col.5, lines 7-9)"	<p>end" do not square with reality.</p> <p>In reality:</p> <ul style="list-style-type: none"> <li>About the location of the "distal end" of endoscope one should judge by its objective.</li> <li>In the US Patent 5,259,364 on the Figure 2, mentioned by Examiner, there is no "distal end" of endoscope.</li> <li>In the US Patent 5,259,364 on the Figure 2 are shown:             <ul style="list-style-type: none"> <li>The distal part of the endoscopic tube (2). There are no any "pleats 52" on it.</li> <li>The proximal part of the endoscopic tube (2) with "pleats (52)".</li> </ul> </li> <li>In the US Patent 5,259,364 on the Figure 1 are shown:             <ul style="list-style-type: none"> <li>the "distal end" of the endoscopic tube (2), that is the head piece (38), which includes the objective,</li> <li>the distal part of the endoscopic tube (2), that is the section above the break,</li> <li>the proximal part of the endoscopic tube (2), that is the section below the break.</li> </ul> </li> <li>In the US Patent 5,259,364 on the Figure 1 there is no "pleats (52)":             <ul style="list-style-type: none"> <li>on the "distal end", mentioned by Examiner,</li> <li>on the distal part of the endoscopic tube (2),</li> <li>on the proximal part of the endoscopic tube (2).</li> </ul> </li> <li>In the US Patent 5,259,364 in column 5, lines 7-9 there is no the statement of Examiner, that "the invaginator would be gathered on the distal end ...".</li> <li>In the US Patent 5,259,364 in column 5, lines 9-11 is said: "The rearward, in FIG.2 lower end of the supply portion 52 is attached to the rear wall of pressure chamber 50". Thus, the supply or storage portion (52) of the invaginator is always located in the chamber (50), i.e. on the proximal part of the endoscopic tube (2).</li> </ul>
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		<ul style="list-style-type: none"> <li>In my application, in contrast to the US Patent 5,259,364, the unevented end (7) of the cylinder of invaginator (23) is joined with the seal (29) on the distal part of the endoscopic tube (3). That is why the 1,5-meters long store of invaginator (23) is always located on the distal part of the endoscopic tube (3) and is moving together with it.</li> </ul>
<p>Examiner's statement, that the invaginator according the US Patent 5,259,364 "defines a gap..."</p>	<p>"As to claims 2, 3 and 8, pleats (52) form a compact hollow cylinder which defines a gap (note space between pleats and endoscope tube in Figure 2) that is maintained under working pressure (col. 5, lines 18-22)."</p>	<p>The statement of Examiner, that in US Patent 5,259,364 (Bob et al.) "pleats (52) form a compact hollow cylinder which defines a gap..." do not square with reality.</p> <p>In reality:</p> <ul style="list-style-type: none"> <li>In US Patent 5,259,364 (see Figure 2) invaginator under the number (52) is represented by the wavy lines. The hollow cylinders are usually represented by straight lines.</li> <li>In US Patent 5,259,364 there are no words "cylinder", "compact", word-combinations "compact cylinder" "compact hollow cylinder" or their synonyms.</li> <li>In US Patent 5,259,364 on Figure 2 there is represented the portion (68) of the pressure chamber (50), limited by the invaginator (52) and the endoscopic tube (2). The presence of a gap between them is ensured not by the compactness of the portion (52), but by the pressure which is feeding in the portion (68) of pressure chamber (50). This pressure must be equal to the pressure in the portion (62) of pressure chamber (50).</li> <li>In US Patent 5,259,364 in case of prevalence of pressure in the portion (62) of pressure chamber (50) over the pressure in the portion (68) of pressure chamber (50), the supply portion (52) of invaginator will adhere to the endoscopic tube (2).</li> <li>In US Patent 5,259,364 in case of prevalence of pressure in the portion (68) of pressure chamber (50) over the pressure in the</li> </ul>

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		<p>supply portion (52) of invaginator and the endoscopic tube (2) will appear, but invaginator (24) will adhere to the outer portion (26).</p> <ul style="list-style-type: none"> <li>• In US Patent 5,259,364 in the indicated col. 5, lines 18-22 there is no the statement of Examiner - there is said that the pressurized fluid can be supplied into the portion (68) of the pressure chamber (50).</li> <li>• In US Patent 5,259,364 the working pressure arrives into the portion (68), then into the gap space (44) and then inevitably gets into the intestine (14). The value of working pressure is 0,35 bar. The obvious threat of intestines ruptures by this pressure excludes its use outside the closed cavity.</li> <li>• In my application for formation of compact hollow cylinder (23) from a thin-wall tube the press-mold and high temperature are used (see my letter from February 13, 2003). Formation of the gap (25) is ensured by the die, which diameter exceeds the diameter of the distal part of endoscopic tube (3). By the compactness the hollow cylinder (23) resembles the cigar.</li> </ul>
Formulating of claim 4.	<p><i>"As to claim 4, the distal end (38) of the endoscope tube encloses a camera and is thus inherently sealed"</i></p>	<ul style="list-style-type: none"> <li>• In US Patent 5,259,364 the camera chip is installed into the head piece (38).</li> <li>• In my application claim 4 declares the movable seal (29) between the endoscopic tube (3) and the movable unevverted end (7) of the invaginator (23).</li> <li>• I thank You for the constructive observation and propose the amended claim 4:  <i>4. The endoscope according to any of claims 1 to 3, further comprising a seal between the endoscopic tube and the unevverted end of said invaginator.</i></li> </ul>

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Novelty of claim 5.	<i>"As to claim 5, note shell (50)."</i>	<ul style="list-style-type: none"> <li>• In my application, due to the internal transverse pleats (48) of the external cover of endoscopic tube (3), as well as due to the widerfings and narrowings (24) of the diameters of cylinder (23), the distal part of endoscope becomes extremely flexible.</li> <li>• In my application the conducting of endoscope with extremely flexible distal part along the rectum (which has a form of ampoule with diameter till 8 cm) into the sigmoid intestine is ensured by the shell (22) (see Fig. 1b, 1c; page 5 lines 38-39).</li> <li>• In my application the shell (22) serves as a sheath-conductor of invaginator (23) and of the distal part of endoscopic tube (3) along the rectum.</li> <li>• In US Patent 5,259,364 there is no neither constructional, nor functional analogue of the shell (22). The object (50) is an out-organ container for the placing of:           <ul style="list-style-type: none"> <li>• means (70),</li> <li>• roller pairs (72),</li> <li>• annular seal (58),</li> <li>• supply portion (52) of invaginator.</li> </ul> </li> <li>• In US Patent 5,259,364 the pressure chamber (50) is not intended for the insertion into rectum.</li> </ul> <p>I propose the amended claim 5:</p> <p><i>5. The endoscope according to any of claims 1 to 3, further comprising a shell of said invaginator, commensurate to the diameter of said invaginator and to the length of rectum.</i></p>
The main point of the term <i>preservative</i> in claim 6 and part of claim 7.	<i>"As to claims 6 and 7, endoscopic tube (2) inherently comprises an outer protective</i>	<ul style="list-style-type: none"> <li>• The preservative is the removable object by its definition.</li> <li>• In my application claims 6 and 7 declares the separate from the endoscopic tube (3) subject matter - the distal preservative (26) (see Figure 1c, 1f; page 7 line 23; page 3 lines 23-25).</li> </ul>

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	<i>sheath which meets the limitation of a preservative."</i>	<ul style="list-style-type: none"> <li>In my application removable preservative (26) isolates the "outer protective sheath" of the endoscopic tube (3), which one was opposed by Examiner to the preservative (26).</li> <li>In my application the preservative (26) "protect the patient from infections seated in endoscopic tube 3, but tube 3 - from getting contagious during endoscopy." (page 6, lines 27-29). Preservative (26), in combination with others elements, allows repeatedly use the endoscopic tube (3) without disinfection.</li> <li>In US Patent 5,259,364 there is no preservative of the distal part of endoscopic tube (2).</li> </ul>
Novelty of claim 9.	<i>"As to claim 9, note seal (58)."</i>	<ul style="list-style-type: none"> <li>In US Patent 5,259,364 the seal (58) pressurizes the cavity of unevrteed part of invaginator.</li> <li>In my application seal (13) pressurizes the cavity of everted part of invaginator.</li> </ul>
The main point of the term <i>tip</i> and novelty of claim 11.	<i>"As to claim 11, note tip (38)."</i>	<ul style="list-style-type: none"> <li>The tip, as well as the preservative, is removable object by its definition, for example, the tip of fountain-pen.</li> <li>In US Patent 5,259,364 the <i>head piece</i> (38) inheres in the tube (2) as a head in a body.</li> <li>In my application is claimed the tip (6), which, following the preceding analogue, is the "hat" of the head of endoscopic tube (3).</li> <li>In my application the ability to remove the tip (6) is confirmed by its belonging to the disposable cartridge (see Figures 1c, 1f, page 3, lines 24-25, page 5 lines 8-10).</li> </ul>
The main point of the term <i>tip</i> and novelty of claim 12.	<i>"As to claim 12, a protective glass is inherent since a camera for viewing is located in the tip (38)."</i>	<ul style="list-style-type: none"> <li>The tip, comprising the glass, is removable object by its definition.</li> <li>In US Patent 5,259,364 there is no tip of endoscopic tube (2).</li> <li>In US Patent 5,259,364 the <i>head piece</i> (38) is not removable.</li> <li>In my application in claim 11 is claimed the removable tip (6) of the endoscopic tube (3).</li> <li>In my application in claim 12 is claimed the removable tip (6) according to claim 11 with the protective glass (33).</li> </ul>



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		<p>The removable tip (6) with glass (33) according to claim 12 is illustrated on Figure 1f and described on page 3, lines 27-28; page 6, line 38; page 7, line 30).</p> <p>At the same time, taking into account the plurality of variants of interpretations of the term <i>tip</i>, herewith I propose the amended claim 11:</p> <p><i>11. The endoscope according to any of claims 1, 2, 3, 7, 8, further comprising a removable tip of the endoscopic tube.</i></p>
Formulating of claim 20.	<p>"As to claim 20, the invaginator (24) is cylindrical (i.e. shape of a cylinder/piston unit)."</p>	<ul style="list-style-type: none"> <li>• There is known very many cylindrical objects. Under the cylinder-piston unit is known the concrete construction, which include two inherent elements - cylinder and its hermetic piston. The pressure, which is feeding into cylinder, realizes the job of lineal displacement of piston or cylinder.</li> <li>• In the US Patent 5,259,364 on Fig 1 and 2 the cylindrical invaginator (24) has no piston.</li> <li>• In the US Patent 5,259,364 is not said, that the cylindrical invaginator (24) is the part of cylinder-piston unit.</li> </ul> <p>I thank You for the constructive opposition, the amended claim looks like as follows:</p> <ul style="list-style-type: none"> <li>• <i>An endoscope comprising a mechanism for introduction of an endoscopic tube, which is a cylinder-piston unit, connected to the pressure of gas or liquid.</i></li> </ul>

According to item 14.

Subject of discussion:	Examiner on June 9, 2003:	Applicant on September 3, 2003:
Novelty of claim 16.	<p>"Claim 16 is rejected under 35 U.S.C. 103 (a) as being unpatentable over Matasov (SU 1522466) in view of Wilk et</p>	<ul style="list-style-type: none"> <li>• The SU Inventors Certificate No. 1522466 was published after October 3, 1997 (see PCT Gazette 15/1999 from April 15, 1999, publication WO99/17655) and therefore is not prior art, but the component part of my application.</li> <li>• Thus, SU Inventors Certificate No. 1522466 in view of U.S. Pat. 5,396,879 can not discredit the novelty of my invention.</li> </ul>

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	<p><i>al. (U.S. Pat. 5,396,879)</i></p> <p><i>and further as being unpatentable over Bob et al. in view of Wilk et al."</i></p>	<ul style="list-style-type: none"> <li>• In my application for bending of distal end of the endoscopic tube (3), which repeats the colon curves, there are described the distal drives of traction lines in the shape of classical cylinder-piston unit (claim 16).</li> <li>• Under the cylinder-piston unit is known the classic construction, which includes two inherent elements - cylinder and its hermetic piston. The pressure of fluid, which is feeding into cylinder, realizes the job of lineal displacement of piston or cylinder.</li> <li>• In the U.S.Pat. 5,396,879 is described the distal drive on the base of solenoid, whose tiny force could not ensure the bending of distal end of endoscopic tube (3), which repeats the colon curves.</li> <li>• U.S.Pat. 5,259,364 in view of U.S.Pat. 5,396,879 could not serve as the prior art, because not one from these patents do not include not one of the subject matters of claims of my application.</li> </ul> <p>I thank You for the observation, the amended claim looks like as follows:</p> <ul style="list-style-type: none"> <li>• <i>The endoscope according to any of claims 1, 2, 3, 7, 8, wherein the endoscopic tube further comprises a distal drives of a traction lines, bending its distal end, which are cylinder-piston units, connected to the pressure of gas or liquid.</i></li> </ul>
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According to item 15.

The claim 17 is withdrawn from Claims.

According to item 16.

Examiner asserts, that "Applicant relies heavily on disclosed subject matter".

In this connection I kindly ask to draw the attention, that all three Examiner's statements, concerning the claims 1, 2 and 3, do not square with reality. They are as follows:

1. Statement, that the invaginator according to US Patent 5,259,364 (Bob et al.) "would be gathered on the distal end" of endoscopic tube.

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2. Statement, that in US Patent 5,259,364 "pleats (52) form a compact hollow cylinder which defines a gap".
3. Statements, that in my application "the working pressure keeps the gap 25" and "the working pressure applied to gap 25".

The persevering reiteration of these three statements, as well as raising of the fourth unfounded statement - about the publication of SU Inventor's Certificate № 1522466 on July 15, 1989 - I am crediting with the infringement by Examiner of 35 U.S.C. 102 and with illegal grant of US Patent 6,485,409 (Voloshin et al.)

In connection with grant of US Patent 6,485,409, please, note that:

- US Patent 6,485,409 (claims 4, 5, 10) comprises invaginator, gathered on the distal part of endoscope.
- More than one year prior the date of patent application 09/646,941, according which the US Patent 6,485,409 was granted, there was printed publication WO 99/17655 of my application, which describes the endoscope with invaginator on its distal part (see PCT/LV98/00006 page 1 lines 12-14, 18-21, 31-35; page 3 lines 3-4, 17-19, 27-29; page 5, lines 7-9; page 7 lines 38-40; page 9 lines 11-13; page 10, lines 1-3; Fig. 1c, 1e, 1f).
- In accordance with 35 U.S.C. 102 my patent application 09/509,377 comprises the SU Inventor's Certificate No. 1522466 with priority from August 27, 1978, wherein is firstly described the colonoscope with invaginator, gathered on the distal part of endoscopic tube.
- Examiner at the same time has examined the patent application 09/646,941 and my application 09/509,377, as well as made the International Search according the International application No. PCT/IL00/00017, which one had a continuation in the patent application 09/646,941.
- In the course of International search of International application No. PCT/IL00/00017 Examiner opposed to it the US Patent 5,259,364 (Bob et al.), but on November 26, 2002 granted the US Patent 6,485,409. In the US Patent 6,485,409 the US Patent 5,259,364 is mentioned as a cited reference.

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These objectives have been achieved by the fact that the claimed endoscope comprises:

- an invaginator made of everting tube, arranged by pleats, formed in the shape of compact hollow cylinder;
- a disposable cartridge combining the invaginator with auxiliary elements;
- an endoscopic tube ensuring fixation of a cartridge;
- a mechanism for introduction of tube, ensuring together with a cartridge insertion of a tube;
- a system of extraction-intraction of traction lines ensuring bending of the tube's distal end with hydro-manual or pneumo-manual or hydraulic or pneumatic drive;
- a hydraulic or pneumatic intensifier of introduction and extraction of biopsy forceps and hydraulic or pneumatic intensifier of traction line of biopsy forceps.

A compact hollow cylinder of the invaginator can be formed of tightly compressed in longitudinal and transverse directions pleats of different forms of an eversible thin-walled tube placed at any angles with the longitudinal axis of an endoscopic tube. The cylinder has recurrent narrowings of an external diameter and widenings of its internal diameter. The stability of diameters depends on the compactness of the cylinder. In one of the embodiments the definite compactness of cylinder ensures the gap with endoscopic tube during their joining and in the process of invagination, in the other - only during the joining. There are possible also the interim variants of embodiments.

A disposable sterile cartridge for invagination consists of a shell which has a projection at its proximal end, comprising: an invaginator; a compressed spring; its fixator; a spring distancer in which the distal seal of the endoscopic tube is located, which is joined to an uneverted end of the invaginator; a preservative of the distal part of the endoscopic tube joined at the proximal end to a spring stop, but at the distal end - to the tip with elements for hermetic joining to the endoscopic tube, while on the shell is located a proximal seal of the endoscopic tube with the anal dilator having the channel in its wall, but at the distal end of the shell the everted end of the invaginator is fastened. In addition to elements for hermetical joining to the endoscopic tube, the tip may have a protective glass and a channel for glass washing.

An endoscopic tube is supplemented with: - an internal transverse pleats of its external cover; - two air-ducts, the larger one has a lateral opening into the cavity of the proximal seal of the disposable cartridge for invagination, but the smaller - into the cavity of distal and proximal preservatives; - areas for hermetical fixation of preservatives' ends; - a proximal preservative.

The mechanism for introduction of the endoscopic tube consists of the cylinder with two pistons, which are interconnected with distancers and an elastic tube. The cylinder is joined with the cartridge for invagination of the endoscopic tube. The cavity between pistons and the elastic tube is connected to the source of pressure or atmosphere (negative pressure) through the cock. The cavity between the distal piston and the proximal seal of the endoscopic tube through the cock is connected to the source of negative pressure or atmosphere (overpressure). The cocks can be placed in the pedals but the spring, which returns pistons to their home position can be located in the cavity between the proximal seal of endoscopic tube and the distal piston.

The system of extraction-intraction of traction lines ensuring management over the endoscopic tube's distal end, has a hydro-manual or pneumo-manual or hydraulic or pneumatic drive and creates suction at the distal end of traction lines. The system includes means of overpressure and negative

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## **Endoscope**

### **with disposable cartridge for the invagination of endoscope tube**

This is the continuation of application PCT/LV98/00006 based on the priority applications  
P-97-190 from 03.10.97 (LV) and P-98-188 from 23.09.98 (LV).

#### **BACKGROUND OF THE INVENTION**

##### **1. Field of the Invention**

The invention relates to the field of medicine, namely to colonoscopy and enteroscopy, but can  
also be used for industrial endoscopes.

##### **2. Description of Background Art**

The common feature of the endoscope, proposed in present application and of endoscopes  
according to known patents is a tube, eversible under fluid pressure. The inflated and everted  
tube invaginates an endoscope tube into explored channel and therefore was named by me as  
invaginator. The exploitation of invaginator is effective in case when it everts close to the  
objective and does not cover the latter.

The fluid pressure causes not only inflation and eversion of invaginator, but also its tight  
engagement with the endoscope tube. As a result of this engagement an everted part of  
invaginator becomes twice shorter than the endoscope tube.

U.S. Pat. 4, 321,915 to Leighton et al., U.S. Pat. 4,615,331 to Kramann and U.S. Pat. 5,259,364  
to Bob et al., whose disclosures are incorporated herein by references, illustrate the attempts to  
overcome the effect of invaginator's engagement with an endoscope tube.

Invaginator according to the US Pat. 4,321,915 is mono-layered. To remove the double lag of  
invaginator there is suggested by the periodical change of pressure and vacuum and by  
extracting of endoscope tube till the moment when its objective coincides with the place of  
invaginator's eversion. But the investigated channel is tortuous and invaginator is a thin-walled  
tube. As a result together with the endoscope tube will be extracted also the invaginator. It  
seems to be complicated also the coincidence of objective together with the place of  
invaginator's eversion.

In the device according to US Pat. 4,615,331 invaginator is placed on the endoscope tube by  
long overlying parallel layers. In this connection the place of invaginator's eversion periodically  
moves away from the objective. The more important defect of multi-layered invaginator is

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inconsequent unreeling of its layers. The premature eversion of lower layer will exclude or complicate eversion of others.

In the device according to US Pat. 5,259,364 the end of uneverted part of invaginator is attached to a chamber, which is an extra-organ storage of the supply portion of invaginator. The problem of engagement of the uneverted part of invaginator with the endoscope tube authors of US Pat. 5,259,364 propose to solve by feeding of working pressure into the uneverted part of invaginator. The working fluid pressure according to data of Gründl, Bob and Bob is varying from 0,4 till 1,2 bar (see US Pat. 5,586,968), but the uneverted part of invaginator, in spite of declaratory authors' assurance, inevitably communicates with the intestinal cavity. It is known that bursting of intestine starts at pressure of 0,17 bar and it bursts under the pressure of 0,235 bar (see [www.anastomos.narod.ru/ourresult.htm](http://www.anastomos.narod.ru/ourresult.htm)). In addition to safety problem the US Pat. 5,259,364 does not solve the problem of displacement of invaginator's uneverted part from chamber to objective.

Thus, all known endoscopes with invaginator are insufficiently effective or dangerous.

The endoscope tube together with invaginator repeat all curves of explored channel. But bending of tube distal end is possible only till the definite number of curves. This is the second drawback of existing colonoscopes. Tube's end is bent by rotating of two rollers each connected to its pair of traction lines. Springs, comprising traction lines, on the distal end are continued by channels in the wall of cardan-jointed rings. Ends of traction lines are soldered to the distal ring of the cardan executive mechanism for bending the tube distal end. Outward extraction of traction line from the spring decreases gaps between cardan rings thus forming a small radius of a curve. At that the distal cardan ring pulls the opposite traction line in distal direction, thus ensuring an increase of space between rings. Difference of lengths of big and small half-circumferences of tube's curve is a product of  $\pi$  and diameter of an endoscope tube. Japanese authors point out that when 3-4 loops are formed, the distal end of an endoscope is was blocked, but biopsy forceps continued to function. This difference is explained by L. Aler formula

$$\frac{Q_1}{Q_2} = e^{\alpha \cdot f}$$

where: « $Q_1$ » - manual power realizing traction lines extraction; « $Q_2$ » - remaining from « $Q_1$ » power, attached to a distal cardan ring or cutters of biopsy forceps; « $e$ » - basis of natural logarithm; « $\alpha$ » - traction line rotations in radians; « $f$ » - friction index between a traction line and a spring. Under fixed values « $Q_1$ » and « $f$ », value « $Q_2$ » depends on value « $\alpha$ », but for two

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consecutively connected traction lines of an endoscope the latter is twice as large as for one line of biopsy forceps.

The third drawback of known endoscopes is the problem of its maintenance. For recurrent use an endoscope tube is washed, disinfected and sterilized. However, there are reported cases of infecting patients with AIDS and other infections after endoscopy.

It has been practically proved that if an endoscope tube has more than 3-4 loops, it is impossible to introduce biopsy forceps into it and to take biopate. This is the fourth drawback of the prototype.

#### SUMMARY OF THE INVENTION

The invention mainly pertains to the field of medicine and particularly is intended for the early diagnostics of colon cancer.

The objectives of the invention have been following: - ensure reliability, and easiness of introduction of endoscope tube into colon or others long flexuous channels; - ensure bending of the distal end of endoscope tube in flexuous channels; - make maintenance of an endoscope more convenient; - perform biopsy in flexuous channels. Implementation of these objectives will make colonoscopy available to any physician and make it easier for experienced endoscopists.

As the base for all variants of the construction of present invention serves an endoscope with invaginator, whose uneverted end is coupled with the distal part of endoscope tube, at that the invaginator is made by pleats and in compact state is held on said distal part.

In the simplest variant of present invention, the uneverted part of invaginator is enclosed into the everted one, and the end of the everted part is fixed on a seal of endoscope tube and connected to fluid pressure.

In preferred embodiments of present invention the invaginator is made in the form of hollow compact flexible cylinder which has a gap with a preservative of the distal part of endoscope tube. A compact hollow cylinder of the invaginator is formed of tightly compressed in longitudinal and transverse directions pleats of different forms of an eversible elastic tube placed at any angles with the longitudinal axis of an endoscope tube. For its flexibility the cylinder could have recurrent narrowings of an external diameter and widenings of its internal diameter.

Preferred embodiments of present invention comprise a disposable sterile cartridge for the invagination of endoscope tube, the cartridge could comprise: - a shell which has a projection at its proximal end, wherein could be enclosed: a preservative of the distal part of endoscope tube

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which could be joined at the proximal end to a spring stop; a compressed spring; a spring  
distancer in which is located a distal seal of the endoscope tube coupled to an uneverted end of  
the invaginator; a fixator of compressed spring; an invaginator in the form of a hollow compact  
cylinder, which has a gap with preservative and could comprise a recurrent narrowings of an  
5 external diameter and widenings of its internal diameter, at that the everted end of invaginator is  
fastened on the distal end of said shell; - a proximal seal of the endoscope tube fastened on the  
distal end of said shell; - an anal dilator having a channel in its wall; - a tip of said endoscope  
tube, coupled with the distal end of said preservative, which one (the tip) has a protective glass,  
a channel for glass washing and blowing of intestine, an element for hermetic joining to the  
10 endoscope tube.

In preferred embodiments of present invention the cartridge for invagination of endoscope tube  
could be attached to a mechanism for its introduction. The mechanism for introduction could  
comprise a cylinder with two pistons, which are interconnected with distancers and segment of  
15 an elastic tube, but a cavity between them through a pedal cock communicates with fluid  
pressure, while a cavity between a proximal seal of the endoscope tube and a distal piston  
comprises a spring which returns pistons to their home position and through the pedal cock  
communicates with fluid pressure.

In preferred embodiments of present invention the inserted endoscope tube could comprise for  
coupling with cartridge: - an internal transverse pleats of its external cover, which raise tube's  
flexibility; - two air-ducts, where the larger one has a lateral opening into a cavity of the proximal  
seal of the disposable cartridge for invagination, but the smaller one - into a cavity of distal and  
proximal preservatives; - an areas for hermetic fixation of ends of preservatives; - a proximal  
25 preservative. At that a control block could be made as a desk unit, but the cock, which feeds the  
working pressure into the everted part of invaginator could be placed in pedal.

In preferred embodiments of present invention the system for bending of the distal end of  
endoscope tube in tortuous channels could comprise the sources of fluid pressure, connected to  
30 cavities of elastic tubes. The elastic tubes could comprise springs with traction lines, the tubes  
could be fixed to springs by thread, but the springs could be executed with pitch. The traction  
lines on distal end could be joined with springs, but in the control block - with manual extractors-  
intractors of traction lines, connected with elements ensuring synchronous fluid evacuation from  
the cavity of manually extracted traction line and fluid feeding into the cavity of introduced  
35 traction line. The distal end of tube and traction line could be finished by cylinder and piston or  
the tube could be finished by an elastic element, for example by sylphone, but a traction line  
could be connected with sylphone's distal end. A manual extractors-intractors of traction lines



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could be made in the manner of a rod, but the sources of fluid pressure – in the manner of a piston and cylinder, positioned on the rod. An element ensuring synchronous fluid evacuation from the cavity of extracted traction line and fluid feeding into the cavity of introduced traction line could be made as a pinion mated with cogs of two rods. Each of two pinions is coupled only with its pair of traction lines, that is why bending of the tube's end could be performed in two stages. The cross-piece with a management lever, wherein central part is movably connected with the body of control block, but the ends are attached to four rods, could ensure simultaneous bending of the tube's end in any direction.

In preferred embodiments of present invention in order to conduct biopsy in torturous channels, the insertion and extraction of biopsy forceps could be realized with a help of fluid pressure which is connected through a cock to the cavity of the biopsy channel, the entrance to which is sealed by a seal of biopsy forceps, and at the distal end of which there is a piston of the biopsy channel. At that the biopsy forceps comprise a flexible hermetic tube, which is connected to source of fluid pressure, but the distal end of the tube and traction lines could be finished with a cylinder and a piston. The unit cylinder-piston is possible to replace with a segment of siphon, the end of which is connected to traction line.

The subject of present invention is an endoscope, comprising

- an invaginator whose uneverted end is coupled with the distal part of the endoscope tube, at that said invaginator is held on said distal part of the endoscope tube;
- an invaginator formed of pleats, tightly compressed in longitudinal and transverse directions in a compact hollow cylinder, which has a gap with said distal part of the endoscope tube.

The subject of present invention also is an endoscope with a disposable cartridge for the invagination of endoscope tube, the cartridge comprises: invaginator whose uneverted end is coupled with the distal part of the endoscope tube, said invaginator is formed of pleats, tightly compressed in longitudinal and transverse directions in a compact hollow cylinder, which has a gap with said distal part of the endoscope tube and is held on said distal part.

Both foregoing subjects of invention could also comprise:

- said cylinder of invaginator having narrowings of external diameter and widenings of internal diameter,
- a shell for conducting the distal part of endoscope tube with invaginator along rectum, at that the diameter of said shell is commensurate to the diameter of said invaginator,
- sliding seals of endoscope tube, isolating a cavity of the everted part of invaginator,
- an anal dilator,

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- o said anal dilator with a channel in its wall,
- o a spring of invaginator,
- o a preservative of the distal part of endoscope tube united with tube's tip, at that the proximal end of preservative and the tip have areas for hermetic fixation to the distal part of said endoscope tube,
- o said tip comprises a protective glass and communicates with intestinal cavity,
- o a mechanism for introduction of the endoscope tube which is a cylinder-piston unit having a hermetic cavity, confined by a cylinder, a piston and a segment of an elastic tube connected to fluid pressure,
- o an endoscope tube with an transverse pleats of its external cover, which are directed internally,
- o an endoscope tube with distal drives of traction lines bending its distal end, which are springs executed with pitch and enclosed inside elastic tubes connected to fluid pressure,
- o an endoscope tube with distal drives of traction lines bending its distal end, which are cylinder-piston units connected to fluid pressure,
- o an endoscope tube with distal drives of traction lines bending its distal end, which are sylphones connected to fluid pressure,
- o an endoscope tube with a biopsy channel connected to fluid pressure and a biopsy forceps which are flexible hermetic tube with a biopsy channel's piston on tube's distal end,
- o said biopsy forceps having a distal drive of forceps which is a cylinder-piston unit connected to fluid pressure,
- o said distal drive of forceps which is a sylphone connected to fluid pressure.

The subject of invention also is a method of prophylaxis from getting infected of endoscope tube and patient, the method comprises:

- o hermetic connection of endoscope tube to tube's distal part preservative and to a tip united with said preservative, having a protective glass and communication with intestinal cavity,
- o hermetic connection of said preservative to the uneverted end of invaginator of endoscope tube, which is an elastic tube everted under fluid pressure, the elastic tube is formed by pleats in a compact hollow cylinder which has a gap with said preservative,
- o feeding of fluid pressure through a channel in endoscope tube under the protective glass of said tip.

action of all pressure engaged to tube's

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5 The problem of engagement of the uneverted part of invaginator with the endoscope tube 3 was solved by invaginator formed of pleats tightly compressed in longitudinal and transverse directions in a compact hollow cylinder 23 (see FIG. 2), the cylinder has a gap 25 with the distal part of an endoscope tube 3 and for its flexibility could have a recurrent narrowings of external diameter and widenings of its internal diameter respectively.

Further follows more complicated variants of present invention (see FIG. 2, FIG. 3, FIG. 4) comprising an endoscope tube 3 with control block 2 and communication branch. There are possible, for example, a following constructions. Air-duct 15 and cock 17 positioned on control  
10 block 2 or in pedal, connect source of fluid working pressure with opening 21 into the cavity of seal 13, which communicates with cavity 14 of shell 22. The distal part of shell 22 is commensurable in relation to length and diameter to uneverted part of invaginator 23, but the proximal part - to the compressed spring 10. Everted end 12 of invaginator 23 is connected to shell 22 by ring 16. Invaginator 23 has narrowings and widenings 24, as well as gap 25 with  
15 distal preservative 26, at that the gap 25 is keeping also at working pressure in the cavity 14. Ends of distal 26 and proximal 27 preservatives and corresponding to them places of tube 3 have areas 28 for interconnection and hermetization. Seal 29 on end 7 of invaginator 23 separates cavity 14 from cavity 25, which communicates with the intestinal cavity. A distancer 30 prevents deformation of seal 29 by spring 10. Ends of compressed spring 10 are based on  
20 distancer 30 and stop 11 at the end 28 of preservative 26. Stop 11, in its turn, is positioned on the projection 31 of shell 22. The distal end of preservative 26 ends with tip 6 with channels 32 for washing of protective glass 33 and blowing-up of intestines, as well as an element for connection to endoscope tube 3. On the border of narrow and broad parts of shell 22 there is an area of intermediate diameter with indented elastic ring 34 for fixation of compressed spring 10.  
25 Channel 35 of anal dilator 19 is used for decompression of intestines during intubation. In the tube 3, besides the enumerated, there are elastic tubes 36, 37 comprising springs 38, 39 and traction lines 40, 41. Tubes 36, 37 are connected to springs 38, 39 with thread 42. Near mechanism 43 for bending the distal end of tube 3, ends of tubes 36, 37 are closed with plugs 44, which also connect springs 38, 39 with traction lines 40, 41. Proximal ends of tubes 36, 37  
30 are connected with sources 45 of fluid pressure. Proximal ends of traction lines 40, 41 are connected with their manual extractors-intractors 46, but the latter - with element 47 which ensures synchronous evacuation of fluid from the cavity of the extracted traction line 40 and feeding of fluid into the cavity of the introduced traction line 41.

35 Endoscope tube 3 has an internal pleats 48 of its external cover, air-duct 49 with two openings 50 designed for vacuum fixation of preservatives 26, 27 to tube 3 and also has a removable

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sleeve gasket 51. Control block 2 has a cock 52 of an air-duct 49. Seal 13 is hermetically connected to a mechanism 53 for introduction of endoscope tube 3. A mechanism 53 for introduction of tube 3 is operated by pedal 54 but lever 55 realizes bending of tubes end. Cylinder 56, two pistons 57, distancers 58 and segment of an elastic tube 59 confine a cavity 60, which is connected with source of fluid pressure by means of cock in pedal 54. Cavity 61 comprises return spring 62 and is connected with source of fluid pressure by means of cock in pedal 54. Seal 64 and nut 65 are mounted on biopsy forceps 63, but piston 66 is positioned at their distal end. Seat for seal 64 and nut 65 is located at entry 67 to biopsy channel, which is positioned with cock 68 on control block 2. Sylphon 69, which serves as a source of fluid pressure in the intensifier of traction line of biopsy forceps 63, could be combined with its handle.

Marks made on preservative 27 and tube 3 serves for their correct positioning. Then mechanism 53 is mounted on tube 3 and cartridge for invagination is fixed. Pressing of cock 52 will ensure vacuum fixation of preservatives 26, 27 to tube 3. After introduction of seal 13 into cylinder 56 endoscope preparation for work is completed.

After the patient has been placed on an endoscope table, a cartridge is oiled and introduced into the rectum and its ampoule is examined as if with a rigid rectoscope. The fluid pressure in cavity 14 is fed by pressing the cock 17 thus releasing the distancer 30 from coupling with fixator 34 and shell 22. Thereby spring 10 is released and it is possible to proceed with invagination of tube 3. Eversion of invaginator 23 and introduction of tube 3 into the colon occurs under fluid working pressure in cavity 14 at the moments of pressing pedal 54. During the endoscopy procedure intestines are to be distended. Gas into intestines is constantly supplied through gas/liquid channel of tube 3 and through channel 32 of tip 6 thus preventing penetrating of intestinal content under a protective glass 33. Gas evacuation from intestines occurs through a channel 35 of anal dilator 19.

Bending of mechanism 43 is realized by means of fluid pressure sources 45, manual extractors-intractors 46 of traction lines 40, 41 and by means of elements 47 which ensure evacuation of fluid from the tube 36 which comprises extracted traction line 40, and feeding of fluid in the cavity of tube 37 containing introduced traction line 41. As a result of fluid evacuation the elastic tube 36 and spring 38 are shortened. Considering, that their distal end is connected with traction line 40, this shortening relieves its manual extraction. Fluid pressure in tube 37 the latter and spring 39 elongates towards executive mechanism 43 thus relieving manual intraction of traction line 41. Thread 42 twisted on tubes 36, 37, connects them with springs 38, 39. Thus, evacuation and feeding of fluid ensure application of powers to distal ends of traction lines 40 and 41;

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manual extraction and intraction of traction lines 40, 41 creates synchronous efforts on their proximal ends. Mechanism 43 of tube 3 is bent downwards by the above-mentioned method. During bending of mechanism 43 upwards, all above enumerated elements are moved in opposite directions, but bending of mechanism 43 to the left and to the right is implemented by  
5 the second pair of traction lines, which work similarly. In intermediate positions mechanism 43 is bent by interchangeable application of both pairs of traction lines. Element 47 made in the shape of a crosspiece with lever 55 ensures simultaneous bending of mechanism 43 in any direction.

As during colonoscopy tube 3 repeats all natural flexures of the colon its extubation must not be  
10 accelerated. Anal dilator 19 through which extubation is to be conducted eliminates unpleasant sensations caused by this process.

The most practically important version of the invention is a colonoscope with endoscope tube 3 without biopsy channel. A disposable cartridge ensures an available to all and atraumatic  
15 transportation of tube 3 in the colon, preservatives 26, 27 protect a patient from infections seated in endoscope tube 3, but a tube 3 - from getting contagious during endoscopy. The management ergonomics of such colonoscope also makes it available to any physician: during endoscopy a physician in sedentary position, watches the screen, presses pedal cock 17 with one foot, pedal 54 with another, the right hand controls lever 55, but in case of necessity  
20 washes the protective glass 33 by pressing on the cock with the left hand. Such colonoscope is necessary firstly for family doctors, gastroenterologists and surgeons for regular screening of colon cancer. Having selected "suspicious" patients out-patient physicians will direct them to an in-patient clinic for conducting biopsy and other thorough examination.

For realization of biopsy a cartridge with tip 6, without glass 33 is used. Having exhausted the possibility of manual insertion of forceps 63, it is necessary by means of seal 64 and nut 65 to  
25 hermetically seal entry 67 into the biopsy channel and connect it by means of cock 68 to the source of fluid pressure. Further insertion of forceps 63 is performed by their manual intraction and due to fluid pressure on piston 66, but extraction - by switching cock 68 in the position  
30 "vacuum" and manual extraction of forceps 63. Due to location of source 69 of fluid pressure of traction line intensifier in the handle of forceps, taking of biopate is made as previously - approach of rings ensures movement of the traction line inwards, but detachment - extraction of the traction line.

35 Specifications of graphic materials' marks on FIG.1-5:

- 2 - control block with communication branch;
- 3 - endoscope tube;
- 4 - everted part of invaginator (on FIG. 5 only);

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- 5 - source of working pressure in cavity 14 (on FIG. 5 only);  
6 - tip of endoscope tube 3;  
7 - uneverted end of invaginator 23;  
8,9 – rings at the end 7 of invaginator (on FIG. 5 only);  
5 10 - compressed spring;  
11 - stop for spring 10;  
12 - everted end of invaginator 23;  
13 – proximal seal of tube 3;  
14 - cavity of everted part 4 of invaginator 23;  
10 15 – air-duct for feeding fluid working pressure into cavity 14;  
16 - ring, fixing end 12 of invaginator 23;  
17 - cock of air-duct 15;  
18 – manometer (on FIG. 5 only);  
19 - anal dilator;  
15 20 – rectum (on FIG. 5 only);  
21 – air-duct 15 opening on tube 3;  
22 - shell of cartridge for invagination;  
23 - invaginator formed in a compact flexible cylinder;  
24 - narrowings and widenings of cylinder of invaginator 23;  
20 25 - gap (cavity) between cylinder of invaginator 23 and preservative 26;  
26 - distal preservative of tube 3;  
27 - proximal preservative of tube 3;  
28 - areas on tube 3 and at the ends of preservatives 26, 27 for their hermetic connection;  
29 – distal seal between tube 3 and end 7 of invaginator 23;  
25 30 - distancer between spring 10 and invaginator 23 comprising seal 29;  
31 - projection on shell 22 for stop 11;  
32 - channel in tip 6;  
33 - protective glass of tip 6;  
34 - elastic ring, fixing spring 10 in compressed state;  
30 35 - channel in anal dilator 19;  
36 - lower elastic tube of extractor-intractor of traction lines;  
37 - upper elastic tube of extractor-intractor of traction lines;  
38 - lower spring of extractor-intractor of traction lines;  
39 - upper spring of extractor-intractor of traction lines;  
35 40 – lower traction line of extractor-intractor of traction lines;  
41 – upper traction line of extractor-intractor of traction lines;

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- 
- 42 - thread fixing elastic tubes 36, 37 to springs 38, 39;  
43 - mechanism for bending of distal end of tube 3;  
44 - plug closing tubes 36, 37 and connecting springs 38, 39 with traction lines 40, 41;  
45 - sources of fluid pressure;  
5 46 - manual extractors-intractors of traction lines 40, 41;  
47 - element for extraction-intraction of one or two pairs of traction lines;  
48 - pleats of external cover of tube 3;  
49 - air-duct into cavity of preservatives 26, 27;  
50 - distal and proximal openings of air-duct 49 on tube 3;  
10 51 - sleeve gasket;  
52 - air-duct 49 cock on control block 2;  
53 - mechanism for insertion of endoscope tube 3;  
54 - pedal for switching on mechanism 53;  
55 - lever of element 47, made in a shape of cross-piece;  
15 56 - cylinder of mechanism 53;  
57 - pistons of cylinder 56;  
58 - distancers between pistons 57;  
59 - segment of elastic tube, attached to pistons 57;  
60 - hermetic cavity, enclosed by segment of elastic tube 59 and pistons 57;  
20 61 - hermetic cavity, enclosed by seal 13 and distal piston 57;  
62 - spring returning pistons 57 to home position;  
63 - biopsy forceps;  
64 - seal of entry 67 into biopsy channel;  
65 - nut, fixing seal 64;  
25 66 - piston of biopsy forceps;  
67 - entry into biopsy channel;  
68 - cock feeding the fluid pressure into biopsy channel;  
69 - source of fluid pressure connected with cavity of biopsy forceps 63;  
70 - cutters of biopsy forceps 63;  
30 71 - distal intensifier (drive) of traction line of the cutters 70.

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